HOUSE BILL 2126
By Terry

SENATE BILL 2060

By Briggs

AN ACT to amend Tennessee Code Annotated, Title 63, relative to dispensing opioids or benzodiazepines.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 63-1-154, is amended by deleting subsection (a) in its entirety and substituting the following:

(a) Except as provided in § 63-1-313, a health care prescriber licensed under this title may not dispense an opioid or benzodiazepine. This section shall not apply to:

(1) The dispensing of complimentary packages of medicinal drugs that are labeled as a drug sample or complimentary drug to the practitioner's own patients in the regular course of practice without the payment of a fee or remuneration of any kind;

(2) The dispensing of opioids or benzodiazepines in the health care system of the department of correction;

(3) The dispensing of opioids or benzodiazepines in connection with the performance of a surgical procedure performed at a licensed health care facility. The amount dispensed pursuant to this subdivision (a)(3) may not exceed a seven (7) day supply. This exception does not allow for the dispensing of an opioid or benzodiazepine more than seven (7) days after the performance of the surgical procedure;

(4) The dispensing of opioids or benzodiazepines pursuant to an approved clinical trial. For purposes of this subdivision (a)(4), the term "approved clinical trial" means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational

new drug application that is reviewed by the United States food and drug administration;

(5) The dispensing of an opioid drug in a nonresidential substitution-based treatment center for opiate addiction, as defined in § 68-11-1602;

(6) The dispensing of an opioid or benzodiazepine to a patient of a facility that is licensed by the board for licensing health care facilities pursuant to § 68-11-202;

(7) The dispensing of an opioid or benzodiazepine to a patient of a facility licensed under title 33;

(8) The dispensing of an opioid or benzodiazepine by a veterinarian in the course of the veterinarian's practice; and

(9) The dispensing of an opioid or benzodiazepine by a health care prescriber, which provides health care services that meets the requirements established in Section 2 of this act.

SECTION 2. Tennessee Code Annotated, Title 63, Chapter 1, Part 1, is amended by adding the following new section:

(a) In order to dispense opioids or benzodiazepines, a health care prescriber shall:

(1) Purchase all opioids or benzodiazepines from a licensed manufacturer as that term is defined in § 63-10-204 that is licensed by the board of pharmacy or a repackager as defined in 21 U.S.C. § 360eee;

(2) Install computer software that will manage, inventory, dispense, and report all controlled substances dispensed. At a minimum, the software shall:

(A) Be Electronic Prescribing of Controlled Substances (EPCS) certified and have passed the most recent DEA 1311 audit under 21 C.F.R. Part 1311;

(B) Verify registration of health care providers pursuant to subdivision (b)(1);

(C) Generate periodic or on-demand reports regarding controlled substance shipments, inventory levels, and dispensing volume with reports by drug class, health care prescriber, or supplier;

(D) Generate periodic or on-demand reports regarding the percentage of controlled, by schedule, to non-controlled medications over the reporting period;

(E) Generate periodic or on-demand reports regarding manual inventory adjustments;

(F) Store and retrieve electronic inventory counts of medication on hand; and

(G) Submit controlled substance dispensing information to the controlled substances monitoring database under title 53, chapter 10, part 3, according to the requirements of state law;

(3) Be capable of electronically submitting the reports required in subdivision (a)(2) to the department of health;

(4) Dispense opioids and benzodiazepines, in the minimum dosage amounts that a health care prescriber, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease, or symptoms;

(5) Dispense opioids and benzodiazepines in safety-sealed, prepackaged containers stamped with the manufacturer's national drug code (NDC) number;

(6) Periodically administer and record pill-counts for opioids or benzodiazepines in order to monitor patient compliance with the prescription;

(7) Dispense no more than a thirty-day supply at any one time; provided, however, that:

(A) The health care prescriber concludes that providing the patient with a prescription in this manner does not create an undue risk of diversion or abuse; and

(B) If a health care prescriber dispenses to a patient a medication that is classified by the U.S. drug enforcement agency (DEA) as a Schedule III or IV opioid or benzodiazepine and issues a prescription order for the same opioid or benzodiazepine during the same office visit, the health care prescriber may only issue a prescription order that authorizes the patient to receive a grand total of up to a ninety-day supply of the medicine, including both the medication dispensed and prescribed, provided the following conditions are met:

(i) The health care prescriber provides written instructions on each prescription order indicating the earliest date on which a pharmacy may fill the initial prescription. If the authorized fill date for the prescription order is sooner than the date when the entirety of the dispensed medication should have been consumed by the patient, the health care prescriber shall indicate the reason for the early fill authorization in the patient's chart and on the prescription order; and

(ii) The health care prescriber may use the phrase "Do Not Fill Before (insert date)"; and

(C) If a health care prescriber dispenses to a patient a medication that is classified by the U.S. drug enforcement agency as a Schedule II

opioid and issues a prescription order for the same opioid medication during the same office visit, the health care prescriber may only issue a prescription order that authorizes the patient to receive a grand total of up to a ninety-day supply of the medicine, including both the medication dispensed and prescribed, provided the following conditions are met:

(i) The health care prescriber provides written instructions on each prescription order indicating the earliest date on which a pharmacy may fill each prescription. This fill later date on the initial prescription order should be for the first day after the dispensed order ends; and

(ii) The prescriber may use the phrase "Do Not Fill Before (insert date)";

(8) Assure that patients receive medically necessary medication counseling, both written and orally, including information on possible side effects and adverse drug interactions with other medications the patient may be taking; and

(9) Assure that opioids or benzodiazepines are dispensed only to an established patient of the practice by a health care prescriber, or a medical technician working under the direct supervision of a physician.

(b) Manufacturers or repackagers that sell opioids or benzodiazepines to dispensing health care prescribers shall:

(1) Register the name, location, and DEA number of each health care prescriber currently dispensing opioids or benzodiazepines with the board of pharmacy within thirty (30) days of the effective date of this act. Thereafter, register the name and location of each health care prescriber that dispenses

opioids and benzodiazepines to the board of pharmacy within ten (10) business days; and

(2) Report all controlled substance shipments sent to dispensing health care prescribers to the DEA's diversion control program (ARCOS) and to the physician dispensing software application as established in subdivision (a)(2).

(c) The board of pharmacy is authorized to promulgate rules relative to the registration of all dispensing health care prescribers who dispense opioids and benzodiazepines. The board is also authorized to establish a fee for registration, if necessary. All such rules shall be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(d) The department is authorized to randomly inspect clinics where dispensing health care prescribers dispense opioids and benzodiazepines solely for the purpose of determining compliance with the requirements of this section through:

(1) Onsite visits; or

(2) Requests for standardized reports generated by the clinic to be forwarded electronically to the department within five (5) business days of a written request.

(e) Any dispensing health care prescriber that is licensed by the board of pharmacy shall be exempt from the requirements of this section and § 63-1-154(a).

SECTION 3. This act shall take effect January 1, 2017, the public welfare requiring it.